JAN 11 2001 (6)

Supreme Court, U.S.
FILED
JAN 11 2001

No. 00-151

In the Supreme Court of the United States

UNITED STATES OF AMERICA, PETITIONER

v.

OAKLAND CANNABIS BUYERS' COOPERATIVE AND JEFFREY JONES

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE PETITIONER

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51 pp

QUESTION PRESENTED

Whether the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, forecloses a "medical necessity" defense to the Act's prohibition against manufacturing and distributing marijuana, a schedule I controlled substance.

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57 Fed. Reg. (1992):
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H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1 (1970) 4, 21, 22, 34, 35
Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base* (Janet E. Joy, et al. eds. 1999) 36
Wayne R. LaFave & Austin W. Scott, Jr., *Substantive Criminal Law* (2d ed. 1986) 13, 17
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OPINIONS BELOW

The opinion of the court of appeals (App. 1a-11a)[1] is reported at 190 F.3d 1109. The May 13, 1998 memorandum and order of the district court is reported at 5 F. Supp. 2d 1086 (App. 41a-81a). The other opinions and orders of the district are unreported (App. 12a-40a).

JURISDICTION

The judgment of the court of appeals was entered on September 13, 1999. A petition for rehearing was denied on February 29, 2000 (App. 82a). On May 22,

[1] "App." refers to the separately bound appendix to the petition for a writ of certiorari.

2000, Justice O'Connor extended the time within which to file a petition for a writ of certiorari to and including June 28, 2000. On June 19, 2000, Justice O'Connor further extended the time within which to file a petition to and including July 28, 2000, and the petition was filed on that date. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provisions of the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761, are set forth at App. 83a-92a.

STATEMENT

1. a. The Controlled Substances Act (CSA) makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by [21 U.S.C. 801-904]." 21 U.S.C. 841(a)(1); see *United States* v. *Moore*, 423 U.S. 122, 131, 135 (1975).[2] The CSA imposes criminal and civil penalties for violations of the Act, see 21 U.S.C. 841-863, and further gives district courts jurisdiction to enjoin violations of the Act. 21 U.S.C. 882(a).

The CSA classifies controlled substances according to their inclusion in one of five schedules.[3] The listing of a substance in one of the five schedules depends on the extent (if any) to which the particular drug has a cur-

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[2] The CSA similarly makes it a crime to possess any controlled substance except as otherwise authorized by the Act. 21 U.S.C. 844(a).

[3] The Act defines a "controlled substance" as "a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V" of the Act. 21 U.S.C. 802(6).

rently accepted medical use, the level of its potential for abuse, and the degree of psychological or physical dependence to which its use may lead. 21 U.S.C. 812(b). The Act then imposes restrictions on the manufacture and distribution of the substance according to the schedule in which it has been placed. See 21 U.S.C. 821-829.

A drug is included in schedule I, the most restrictive schedule, if it "has a high potential for abuse," "has no currently accepted medical use in treatment in the United States," and has "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(A)-(C). A drug is included in schedule II if it "has a high potential for abuse," but "has a currently accepted medical use in treatment in the United States" or "a currently accepted medical use with severe restrictions." 21 U.S.C. 812(b)(2)(A) and (B). Schedules III through V consist of drugs that similarly have "a currently accepted medical use in treatment in the United States," 21 U.S.C. 812(b)(3)(B), (4)(B) and (5)(B), but have a lower potential for abuse and a more limited degree of dependence than drugs listed in the preceding schedule. 21 U.S.C. 812(b)(3)-(5).

When it enacted the CSA in 1970, Congress specified certain substances to be included in each of the schedules as an initial matter. Pub. L. No. 91-513, Tit. II, § 202, 84 Stat. 1248-1252; see 21 U.S.C. 812(a). Congress classified marijuana and tetrahydrocannabinols as schedule I controlled substances from the outset, see 84 Stat. 1249 (schedule I(c)(10) and (17)), and they have remained schedule I substances ever since 1970. See 21 U.S.C. 812(c) (schedule I(c)(10) and (17)).[4]

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[4] "Marijuana (*cannabis sativa L.*) is a psychoactive drug made of the leaves, flowers, and stems of the Indian Hemp plant. It

The Attorney General may add other substances to the schedules if she finds, pursuant to procedures specified in the Act, that the drugs meet the statutory criteria. See 21 U.S.C. 811; *Touby* v. *United States*, 500 U.S. 160 (1991).

The CSA establishes "a 'closed' system of drug distribution" for all controlled substances. H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 6 (1970); see also *Moore*, 423 U.S. at 141 (The CSA "authorizes transactions within 'the legitimate distribution chain' and makes all others illegal.") (quoting H.R. Rep. No. 1444, *supra*, Pt. 1, at 3). No individual or entity may distribute or dispense a schedule I controlled substance except as part of a strictly controlled research project that has been registered with the Drug Enforcement Administration (DEA) and approved by the Food and Drug Administration (FDA). 21 U.S.C. 823(f); 21 C.F.R. 5.10(a)(9), 1301.18, 1301.32; 28 C.F.R. 0.100(b); see also 21 U.S.C. 355(i) (discussed at p. 6, note 5, *infra*). By contrast, drugs listed in schedules II through V may be dispensed and prescribed for medical use. Physicians, pharmacies, and other legitimate handlers of drugs listed in schedules II through V must, however, comply with stringent statutory and regulatory provisions that mandate registration with the DEA, establish security controls, impose recordkeeping

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derives its psychoactive properties from delta-9-tetrahydrocannabinol (THC), which exists in varying concentrations in the plant, depending on its origin, growing conditions, and cultivation." *National Org. for the Reform of Marijuana Laws* v. *Bell*, 488 F. Supp. 123, 128 (D.D.C. 1980) (three-judge court). In addition to THC, marijuana contains over 400 separately identified chemicals. 57 Fed. Reg. 10,499, 10,500, 10,507 (1992). See also 21 U.S.C. 802(16) (defining marijuana to mean "all parts of the plant Cannabis sativa L").

and reporting obligations, and permit the drug to be distributed and dispensed only pursuant to specified order-form and prescription requirements. See 21 U.S.C. 821-829; 21 C.F.R. 1301-1306.

The CSA also establishes an exclusive set of statutory procedures under which controlled substances that have been placed in schedule I (or any other schedule) may be transferred to another schedule or be entirely removed from the schedules. 21 U.S.C. 811(a). Pursuant to that process, "any interested party" who believes that medical, scientific, or other relevant data warrant transferring marijuana to a less restrictive schedule may petition the Attorney General to initiate a rulemaking proceeding to reschedule marijuana. 21 U.S.C. 811(a). Before initiating such proceedings, the Administrator of DEA, to whom the Attorney General has delegated her authority under the CSA (see 28 C.F.R. 0.100(b)), must request from the Secretary of Health and Human Services (HHS) a scientific and medical evaluation and a recommendation as to whether the substance should be reclassified or decontrolled. The recommendations of the Secretary are binding on the Administrator with respect to scientific and medical matters. 21 U.S.C. 811(b). If the Administrator concludes that there is substantial evidence that the substance should be rescheduled or decontrolled, he shall institute a public rulemaking proceeding on the record. 21 U.S.C. 811(b). Any party aggrieved by a final decision of the Administrator may seek review in the courts of appeals. 21 U.S.C. 877; see, *e.g.*, *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (D.C. Cir. 1994) (upholding Administrator's decision declining to transfer marijuana from schedule I to schedule II).

b. In addition to the restrictions under the CSA, marijuana is subject to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* Under the FDCA, "new" drug includes any drug that "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. 321(p); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629-632 (1973); *United States* v. *Rutherford*, 442 U.S. 544, 546-548, 549-550 n.7 (1979). The FDCA prohibits the "introduc[tion] or deliver[y] for introduction into interstate commerce" of a new drug, absent the submission of a new drug application (NDA) and a finding by the FDA that the drug is both safe and effective for each of its intended uses. 21 U.S.C. 355(a) and (b); *Rutherford*, 442 U.S. at 546.[5] The drug must be proven safe through "adequate tests by all methods reasonably applicable," and it must be proven effective by "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." 21 U.S.C. 355(d).

c. In a statutory provision enacted in 1998 and entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress declared that:

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[5] The FDCA authorizes the Secretary to promulgate regulations for exempting from the new drug restrictions "drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs." 21 U.S.C. 355(i).

(1) certain drugs are listed on Schedule I of the Controlled Substances Act if they have a high potential for abuse, lack any currently accepted medical use in treatment, and are unsafe, even under medical supervision;

* * * * *

(3) pursuant to section 401 of the Controlled Substances Act, it is illegal to manufacture, distribute, or dispense marijuana * * *;

(4) pursuant to section 505 of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 355], before any drug can be approved as a medication in the United States, it must meet extensive scientific and medical standards established by the Food and Drug Administration to ensure it is safe and effective;

(5) marijuana and other Schedule I drugs have not been approved by the Food and Drug Administration to treat any disease or condition;

(6) the Federal Food, Drug and Cosmetic Act already prohibits the sale of any unapproved drug, including marijuana, that has not been proven safe and effective for medical purposes and grants the Food and Drug Administration the authority to enforce this prohibition through seizure and other civil action, as well as through criminal penalties;

* * * * *

(11) Congress continues to support the existing Federal legal process for determining the safety and efficacy of drugs and opposes efforts to circum-

> vent this process by legalizing marijuana, and other Schedule I drugs, for medicinal use without valid scientific evidence and the approval of the Food and Drug Administration.

Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760 to 2681-761.

2. On January 9, 1998, the United States brought this suit in the United States District Court for the Northern District of California seeking an injunction against six marijuana distributors, popularly known as "cannabis clubs," and ten associated individuals, alleging that the defendants' ongoing distribution (and in some cases manufacture) of marijuana violated the CSA. Many such groups formed in the wake of California's Compassionate Use Act of 1996, or Proposition 215, which purports to authorize under state law the possession and cultivation of marijuana for medical purposes upon a physician's recommendation. See Cal. Health & Safety Code § 11362.5(b)(1)(A) and (d) (West 1999).[6]

On May 19, 1998, the district court issued a preliminary injunction under 21 U.S.C. 882(a) that enjoined respondents Oakland Cannabis Buyers' Cooperative (OCBC) and its director and other marijuana distributors from "engaging in the manufacture or distribution of marijuana, or the possession of marijuana with the intent to manufacture and distribute mari-

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[6] Proposition 215, however, neither authorizes the distribution of marijuana for medical purposes nor exempts such conduct from prosecution under California's laws that criminalize the distribution of marijuana. *People* v. *Peron*, 70 Cal. Rptr. 2d 20, 25-29 (1997), review denied, No. A077630 (Feb. 25, 1998). Proposition 215 also does not purport to displace any federal law applicable to marijuana.

juana, in violation of 21 U.S.C. § 841(a)(1)." App. 39a-40a (order); *id.* at 41a-81a (memorandum opinion). The court found it "undisputed that [respondents] distribute marijuana * * * to seriously ill patients or their primary caregivers for personal use by the patient upon a physician's recommendation." *Id.* at 63a. The court also rejected a variety of legal contentions offered by respondents to exempt themselves from the CSA's prohibition against the manufacture and distribution of marijuana, including arguments based on a "medical necessity" theory. *Id.* at 68a-71a. The court noted that the "medical necessity" defense "has never been allowed to exempt a defendant from the criminal laws on a blanket basis." *Id.* at 70a.

Respondents did not appeal the injunction but rather violated it by openly distributing marijuana to numerous persons. App. 21a-23a. On October 13, 1998, the district court issued an order finding respondents in civil contempt. *Id.* at 20a-38a. On October 16, 1998, the district court issued an order denying respondents' motion to modify or dissolve the injunction to include a broad exemption for distribution to persons claiming a "medical necessity" to smoke marijuana. Respondents' motion had requested a ruling permitting them to distribute marijuana to persons who obtained a physician's certificate stating that they need marijuana to alleviate or treat a serious medical condition. See *id.* at 18a-19a (denying motion for modification); *id.* at 7a-8a, 28a-29a (describing proposed "medical necessity" defense).

3. In a per curiam opinion, the court of appeals reversed the district court's denial of the motion to modify the injunction based on a physician's statement of "medical necessity." App. 1a-11a. The court of appeals held that the district court, in construing its equitable power to issue an injunction, erred in not

"tak[ing] into account a legally cognizable defense that likely would pertain in the circumstances." *Id.* at 8a. The court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought." *Id.* at 9a (quoting *Northern Cheyenne Tribe* v. *Hodel*, 851 F.2d 1152, 1156 (9th Cir. 1988)).

The court of appeals further concluded that, in deciding whether to issue or modify the injunction, the district court abused its discretion in not considering what the court of appeals described as "a strong public interest in the availability of a doctor-prescribed treatment that would help ameliorate the condition and relieve the pain and suffering of a large group of persons with serious or fatal illnesses." App. 9a-10a. "Indeed," the court observed, "the City of Oakland has declared a public health emergency" in response to the district court's denial of respondents' motion to modify the injunction to authorize respondents to distribute marijuana. *Id.* at 10a. The court also expressed the view that "[t]he evidence in the record is sufficient to justify the requested modification," and the court had "no doubt that the district court could have modified its injunction, had it determined to do so in the exercise of its equitable discretion." *Ibid.* "[B]y contrast," the court continued, the government had identified no "interest it may have in blocking the distribution of cannabis to those with medical needs, relying exclusively on its general interest in enforcing its statutes." *Id.* at 11a. The court of appeals therefore remanded the matter to the district court "to reconsider" respondents' request for a modification of the injunction to

exempt persons who have a medical need for marijuana. *Ibid.*

4. Following the Ninth Circuit's decision, on May 30, 2000, OCBC filed a motion with the district court to modify the district court's injunction entered on May 19, 1998. On July 17, 2000, the district court granted OCBC's motion. App. 12a-17a. The court explained:

> On remand the government has still not offered any evidence to rebut [OCBC's] evidence that cannabis is medically necessary for a group of seriously ill individuals. Instead, the government continues to press arguments which the Ninth Circuit rejected, including the argument that the Court must find that enjoining the distribution of cannabis to seriously ill individuals is in the public interest because Congress has prohibited such conduct in favor of the administrative process regulating the approval and distribution of drugs.

Id. at 13a. The court therefore stated that, "[a]s a result of the government's failure to offer any new evidence in opposition to [OCBC's] motion, and in light of the Ninth Circuit's opinion, the Court must conclude that modifying the injunction as requested is in the public interest and exercise its equitable discretion to do so." *Ibid.*

The district court accordingly issued an Amended Preliminary Injunction Order which reaffirmed that respondents are preliminary enjoined from manufacturing or distributing marijuana, or possessing marijuana with the intent to manufacture or distribute it, in violation of 21 U.S.C. 841(a)(1). App. 15a-16a. The district court further ordered, however, that

> [t]he foregoing injunction does not apply to the distribution of cannabis by [respondents] to patient-

> members who (1) suffer from a serious medical condition, (2) will suffer imminent harm if the patient-member does not have access to cannabis, (3) need cannabis for the treatment of the patient-member's medical condition, or need cannabis to alleviate the medical condition or symptoms associated with the medical condition, and (4) have no reasonable legal alternative to cannabis for the effective treatment or alleviation of the patient-member's medical condition or symptoms associated with the medical condition because the patient-member has tried all other legal alternatives to cannabis and the alternatives have been ineffective in treating or alleviating the patient-member's medical condition or symptoms associated with the medical condition, or the alternatives result in side effects which the patient-member cannot reasonably tolerate.

Id. at 16a-17a.[7]

SUMMARY OF ARGUMENT

A. 1. A common law defense of "necessity" permits a court or jury to acquit a defendant of a criminal offense based upon a finding that the defendant acted to prevent an evil that is greater than that sought to be avoided by the legislature in criminalizing the conduct at issue. *United States* v. *Bailey*, 444 U.S. 394, 410 (1980). The defense is not available, however, if the statute defining the criminal offense reflects a legis-

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[7] On August 29, 2000, this Court entered an order granting the government's application for a stay of the district court's July 17, 2000, orders, pending appeal of the order to the court of appeals. 121 S. Ct. 21. On December 12, 2000, the court of appeals postponed oral argument on that appeal pending this Court's decision on writ of certiorari here.

lative resolution of the conflicting values at stake or other judgment that precludes the defense. Wayne R. LaFave & Austin W. Scott, Jr., *Substantive Criminal Law* § 5.4, at 627-629 (2d ed. 1986); Model Penal Code § 3.02(1)(a) (1962).

2. The text, structure and purposes of the Controlled Substances Act (CSA) establish a judgment by Congress that necessarily precludes a "necessity" defense to a charged violation of the Act based on an asserted medical need to smoke marijuana. By classifying marijuana as a schedule I controlled substance, Congress, in the text of the CSA itself, has declared that marijuana has no "currently accepted medical use in treatment in the United States" and has no "accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1)(B) and (C). Congress thus has banned the distribution of marijuana for *any* purpose, including purported medical use—"[e]xcept as authorized" by the Act itself (21 U.S.C. 841(a)(1)), *i.e.*, unless the person dispensing the drug is a practitioner registered with the Drug Enforcement Administration to conduct research that has been specifically approved by the Food and Drug Administration (21 U.S.C. 355(i) and 823(f)). The CSA thus leaves no doubt that Congress has considered the possibility of the medical use of marijuana and has specifically rejected it.

3. A "medical necessity" defense also cannot be reconciled with the provisions of the CSA that substantially restrict and control the distribution and use of all controlled substances, even those that are listed in schedules II through V and that therefore have been determined to have an accepted medical use. The CSA requires legitimate handlers of all controlled substances to register with the DEA and follow recordkeeping and reporting obligations, and the Act further requires

manufacturers and distributors to use specified order forms when distributing schedule I or II controlled substances, and requires practitioners who dispense drugs to follow specified prescription requirements. 21 U.S.C. 821-829. The Ninth Circuit's decision countenances the ongoing distribution of marijuana without any of those stringent controls, and thus defeats the CSA's purposes to protect the public from the dangers associated with the abuse of illicit drugs and their diversion from legitimate channels.

4. The asserted defense of "medical necessity" likewise is fundamentally inconsistent with the CSA's provisions that govern the reclassification of controlled substances or their removal from scheduling altogether. Congress in the CSA assigned to the Attorney General, in consultation with the Secretary of HHS, the responsibility to decide whether to reclassify or remove marijuana from schedule I, if she determines that the existing scientific and medical data support the conclusion that marijuana no longer meets the statutory criteria of a schedule I drug. 21 U.S.C. 811(a)-(c). Congress also provided that any final decision by the Attorney General to retain or change the inclusion of marijuana in schedule I would be subject to review by a court of appeals, which must give conclusive effect to the Attorney General's factual findings that are supported by substantial evidence. 21 U.S.C. 877. Those provisions manifest a congressional intent to prevent organizations such as respondents from circumventing and subverting those procedures by attempting to persuade a district court or jury on a case-by-case basis whether the illegal distribution of marijuana is justified because of an asserted medical use for the drug.

5. Finally, a "medical necessity" defense cannot be reconciled with the 1998 statute that Congress passed

in specific response to attempts by States to legalize marijuana use for medical purposes. That statute unambiguously expresses Congress's continued adherence to the position that "marijuana * * * has not been proven safe and effective for medical purposes" and Congress's insistence that marijuana may not be used for asserted medical purposes "without * * * the approval of the Food and Drug Administration" under the FDCA. 112 Stat. 2681-760 to 2681-761.

B. A district court lacks the equitable discretion to craft an injunction that permits the distribution of marijuana for medical use in violation of the Act based on the court's own view that such conduct furthers the public interest. A court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginian Ry.* v. *System Fed'n No. 40*, 300 U.S. 515, 551 (1937); accord *TVA* v. *Hill*, 437 U.S. 153, 194 (1978). This Court adhered to that rule in *United States* v. *Rutherford*, 442 U.S. 544 (1979), in holding that a district court lacked the power to enter an injunction that permitted the use of an unapproved drug, Laetrile, by terminally ill cancer patients. The Court reasoned that the FDCA "makes no special provision for drugs used to treat terminally ill patients," and that a court therefore may not override Congress's policy choice that the drug not be distributed absent a finding by the FDA under the FDCA that the drug is safe and effective. *Id.* at 551.

The CSA likewise "makes no special provision" for marijuana use to treat patients who claim that marijuana is the only drug that will treat or alleviate their medical conditions. Congress already has determined that the illegal use and distribution of marijuana have "a substantial and detrimental effect on the health and general welfare of the American people," 21 U.S.C.

801(2), and that marijuana has no "currently accepted medical use in treatment in the United States"; has no "accepted safety for use * * * under medical supervision"; and is "unsafe, even under medical supervision." 21 U.S.C. 812(b)(1)(B) and (C); 112 Stat. 2681-760 to 2681-761. Congress therefore categorically has banned the unauthorized distribution of marijuana for all purposes, including purported medical uses, outside the strict controls established by the Act. 21 U.S.C. 841(a)(1). A district court may not override those determinations by reweighing the scientific and medical data and social policies considered by Congress, the Attorney General, and the Secretary of Health and Human Services, and concluding that the public interest supports the illegal distribution of marijuana.

ARGUMENT

THE CONTROLLED SUBSTANCES ACT FORECLOSES A "MEDICAL NECESSITY" DEFENSE IN BOTH CRIMINAL AND CIVIL PROCEEDINGS UNDER THE ACT

This case presents the question whether a defendant who violates the prohibitions in the Controlled Substances Act (CSA) on the distribution of marijuana, a schedule I controlled substance, nonetheless may avoid liability under the Act based on a claim that the use of marijuana by the person to whom it is distributed is medically necessary. In recognizing the availability of a common law defense of "medical necessity" under the CSA, the court of appeals has sanctioned the ongoing distribution of marijuana for asserted medical purposes when such conduct otherwise would admittedly violate the Act. Indeed, the decision goes further and relegates to individual district courts and juries the power

to determine in individual cases brought by the government under the CSA whether and the manner in which marijuana can be distributed for an asserted medical use. As we explain below, however, Congress in the CSA has foreclosed a "medical necessity" defense, whether asserted in a criminal prosecution under 21 U.S.C. 841(a)(1) or in a civil enforcement proceeding under 21 U.S.C. 882(a).

A. The CSA's Text, Structure, And Policies Bar A "Medical Necessity" Defense To A Charged Criminal Violation Of The Act

1. The common law defense of "necessity" is often referred to as a "choice of evils" defense. The defense permits a court or jury to excuse a defendant's criminal conduct if the defendant reasonably believes that the conduct was necessary to avert an evil or harm that is more serious than that sought to be prevented by the law defining the criminal offense charged. See *United States* v. *Bailey*, 444 U.S. 394, 410 (1980); Wayne R. LaFave & Austin W. Scott, Jr., *Substantive Criminal Law* § 5.4, at 627-629 (2d ed. 1986) (LaFave); Model Penal Code § 3.02(1)(a) (1962).

A necessity defense has no application, however, in the face of a contrary legislative judgment that the criminal action is not justified by a claimed necessity to commit the prohibited act. "The defense of necessity is available only in situations wherein the legislature has not itself, in its criminal statute, made a determination of values. If it has done so, its decision governs." LaFave 629 (footnote omitted).[8] Thus, "a legislative

[8] Stated differently, criminal conduct may be excused based on necessity only "when a real legislature would formally do the same under those circumstances." *United States* v. *Schoon*, 971 F.2d 193, 196-197 (9th Cir. 1991), cert. denied, 504 U.S. 990 (1992).

purpose to exclude the justification claimed [must] not otherwise plainly appear." Model Penal Code § 3.02(1)(c); see also *id.* (explanatory note) ("The legislature must not have previously foreclosed the choice that was made by resolving the conflict of values at stake."); *United States* v. *Kabat*, 797 F.2d 580, 591-592 (8th Cir. 1986) ("The necessity defense was never intended to excuse criminal activity by those who disagree with the decisions and policies of the lawmaking branches of government: in such cases the 'greater harm' sought to be prevented would be the course of action chosen by elected representatives."), cert. denied, 481 U.S. 1030 (1987). Accordingly, the defense "cannot succeed" if "the legislature ha[s] itself canvassed the issue and determined what the choice should be," because "[t]he legislature, so long as it acts within constitutional limits, is always free to make such a choice and have its choice prevail." Model Penal Code § 3.02(1) (cmt. 2) (footnote omitted).[9]

This Court applied those principles in *United States* v. *Bailey*, *supra*, in considering whether prisoners could

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[9] The Supreme Court of New Jersey similarly has defined the limits of the necessity defense:

> In essence [the necessity defense] reflects a determination that if, in defining the offense, the legislature had foreseen the circumstances faced by the defendant, it would have created an exception. It would have balanced the competing values and chosen the lesser evil. Obviously, then, the defense is available at common law only when the legislature has not foreseen the circumstances encountered by a defendant. If it has in fact anticipated the choice of evils and determined the balance to be struck between the competing values, defendants and courts alike are precluded from reassessing those values to determine whether certain conduct is justified.

State v. *Tate*, 505 A.2d 941, 946 (1986).

avoid criminal liability under 18 U.S.C. 751(a), which prohibits escape from the custody of the Attorney General, based on a defense that the escape was necessary to avoid unsafe prison conditions. The Court held that such a defense was unavailable in that case because the prisoners had failed to surrender or return to custody as soon as the claimed conditions had lost their coercive force. 444 U.S. at 410-415. The Court reasoned that the recognition of a necessity defense in those circumstances would conflict with Section 751(a)'s purpose to guard against the continuing threat to society posed by an escaped prisoner. *Id.* at 412-413. The Court further explained that, although the common law defense "may well have been contemplated by Congress when it enacted [Section] 751(a), * * * some duty to return * * * must be an essential element of the defense unless the congressional judgment that escape from prison is a crime be rendered wholly nugatory." *Id.* at 416 n.11.

2. a. The CSA's provisions leave no doubt that respondents in this case may not invoke a supposed "medical necessity" for individuals to smoke marijuana in certain circumstances to justify the ongoing distribution of marijuana in flagrant violation of the express terms of the CSA. Congress in the CSA has declared that "[t]he illegal * * * distribution[] and * * * improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. 801(2). The CSA therefore makes it unlawful to "manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense" any controlled substance, "[e]xcept as authorized by" the Act itself. 21 U.S.C. 841(a)(1); see *United States* v. *Moore*, 423 U.S. 122, 131, 135 (1975).

Since the enactment of the CSA in 1970, marijuana has been classified as a schedule I controlled substance, a classification which means that marijuana has been found to have a "high potential for abuse," "no currently accepted medical use in treatment in the United States," and "a lack of accepted safety for use * * * under medical supervision." 21 U.S.C. 812(b)(1). In the 1998 legislation entitled "NOT LEGALIZING MARIJUANA FOR MEDICINAL USE," Congress reiterated those findings, and reaffirmed its view that schedule I drugs are "unsafe, even under medical supervision," and that the CSA makes it "illegal to manufacture, distribute, or dispense marijuana." Pub. L. No. 105-277, Div. F, 112 Stat. 2681-760. Moreover, as a schedule I controlled substance, the CSA unequivocally provides that marijuana may not be dispensed to any individual outside of a strictly controlled research project that has been registered with the DEA and approved by the FDA. 21 U.S.C. 355(i), 823(f); 21 C.F.R. 5.10(a)(9), 1301.18, 1301.32; 28 C.F.R. 0.100(b).

Congress thus expressly has considered the possibility of the use of marijuana for medical purposes and has specifically rejected it. In those circumstances, to permit respondents to distribute marijuana for medical use would render Congress's judgment to criminalize the unauthorized distribution of marijuana "wholly nugatory." *Bailey*, 444 U.S. at 416 n.11. It is therefore inconceivable that Congress would have endorsed the illegal distribution of marijuana for medical purposes whenever such conduct was necessary to avert medical harm.

b. The recognition of a "medical necessity" defense also cannot be reconciled with the stringent controls that Congress placed on *all* controlled substances, 21 U.S.C. 821-829, even those drugs listed in schedules II

through V that *have* "a currently accepted *medical use* in treatment in the United States." 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B) (emphasis added). The House Report explains that the CSA "provides for control * * * of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal." H.R. Rep. No. 1444, 91st Cong., 2d Sess. Pt. 1, at 3 (1970); see also *Moore*, 423 U.S. at 141. The House Report further explains that Congress expected that the CSA would "significantly reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control." H.R. Rep. No. 1444, *supra*, Pt. 1, at 6; see also *Moore*, 423 U.S. at 135 (describing the CSA's purpose to guard against the "diversion of drugs from legitimate channels to illegitimate channels").

To those ends, the CSA requires manufacturers, distributors, and dispensers of all controlled substances to register with the DEA. 21 U.S.C. 821, 822(a), 823; 21 C.F.R. 1301. The Act also requires registrants to adopt effective controls to guard against the theft or diversion of controlled substances, 21 U.S.C. 823; 21 C.F.R. 1301.71-1301.76, and authorizes the Attorney General to inspect a registrant's establishment, 21 U.S.C. 822(f), 880. The Act imposes other significant restrictions on the distribution of controlled substances to ensure a closed system of distribution. The Act requires the Attorney General to determine production quotas for schedules I and II controlled substances, 21 U.S.C. 826; 21 C.F.R. 1303; imposes substantial recordkeeping and reporting requirements on registrants, 21 U.S.C. 827;

21 C.F.R. 1304; disallows the distribution of schedule I and II drugs except pursuant to an order form issued by the DEA, 21 U.S.C. 828(a); 21 C.F.R. 1305; and establishes prescription requirements for the dispensing of drugs in schedules II through V, 21 U.S.C. 829; 21 C.F.R. 1306.[10]

The Ninth Circuit's decision completely abandons even any pretense of requiring respondents to comply with those provisions. Instead, it essentially permits respondents to function as an unregulated and unsupervised marijuana pharmacy—one that may distribute an unlimited amount of marijuana to an unlimited number of persons, as long as those persons assert, to the satisfaction of respondents (and later a judge or jury), that marijuana is the most effective drug for a serious medical condition. App. 7a-8a, 9a-10a. The recognition of a "medical necessity" defense not only flouts the CSA's "'closed' system of drug distribution," it also utterly defeats the CSA's purposes to establish a comprehensive and unified approach to "dangerous drug control" and to guard against the risks of drug abuse and the diversion of controlled substances from "legitimate channels into the illicit market." H.R. Rep. No. 1444, *supra*, Pt. 1, at 6.[11] The fact that the Ninth

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[10] The Attorney General also may deny, revoke, or suspend a registration under circumstances specified in the Act. 21 U.S.C. 823, 824; 21 C.F.R. 1301.31-1301.37.

[11] Although the City of Oakland has passed a resolution that purports to establish a "Medical Cannabis Distribution Program" and designates OCBC as the City's agent to administer the program (J.A. 145, 148), respondents do not assert that the City's program comes close to complying with any of the strict controls imposed by the CSA to protect against marijuana abuse or diversion of the drug. Indeed, on several occasions, OCBC dispensed marijuana from its "Budbar" to undercover DEA agents who

Circuit's decision has countenanced respondents' distribution of marijuana, a schedule I drug, without *any* of the stringent controls placed on less restricted drugs listed in schedules II through V, simply highlights the absurdity of suggesting that a "medical necessity" defense can be reconciled with the CSA.

c. The recognition of a "medical necessity" defense under the CSA similarly conflicts with Congress's determination that the controls placed on schedule I controlled substances may not be altered unless and until the Attorney General and the Secretary of HHS follow the statutory procedures specified in the Act for the rescheduling of drugs. The CSA provides that any interested person may petition the DEA to initiate a rulemaking proceeding if he or she believes that medical, scientific, or other relevant data warrant transferring marijuana from schedule I to a less restrictive

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presented a membership card that OCBC had issued to another DEA agent based on a-phony physician statement. See J.A. 47-50, 53-61, 62-66. OCBC also apparently relies on patient-purchasers to determine what type of marijuana is medically appropriate. J.A. 50 ("[T]he OCBC currently had seven kinds of marijuana for sale, all displayed. * * * I then purchased * * * marijuana with 'brand name' of 'Northern Lights.'"); J.A. 60 ("The sales counter * * * contained several small bottles marked 'Small Hash Oil—$30,' and 'Large Hash Oil—$60.' I also observed a small black square substance that was labeled 'Afghani Hash, 20 grams—$400. * * * I asked for one-eighth ounce of the 'House Special.'"); J.A. 65 (When the OCBC clerk "asked me what I wanted to purchase. I pointed to a clear plastic baggie labeled 'Mexican AA-Grade A.'"); J.A. 72 ("I * * * asked to purchase * * * marijuana with the 'brand name' of 'That's Purdy.'"). Moreover, DEA agents visiting OCBC repeatedly detected the smell of burnt marijuana and observed marijuana either being smoked or grown on the premises. J.A. 49-50, 54, 57; see also J.A. 58 (An OCBC clerk "handed me several bags [of marijuana], and informed me that, 'it's really good, I've just smoked some myself.'").

schedule, so as to allow its use for medical purposes under the Act. 21 U.S.C. 811.[12] Moreover, the CSA provides that any final administrative decision declining to reschedule marijuana is subject to review by the courts of appeals, which must uphold the Attorney General's factual findings if supported by substantial evidence. 21 U.S.C. 877. Based on that statutory framework, the courts of appeals uniformly have held that the statutory rescheduling process is the exclusive means by which criminal defendants charged with violating the Act may challenge marijuana's placement in schedule I. See, *e.g.*, *United States* v. *Burton*, 894 F.2d 188, 192 (6th Cir.) ("it has repeatedly been determined, and correctly so, that reclassification is clearly a task for the legislature and the attorney general and not a judicial one"), cert. denied, 498 U.S. 857 (1990).[13]

Here, respondents do not claim that they have petitioned the Attorney General to reschedule or decontrol marijuana on the ground that the drug has a currently accepted medical use. Cf. *Bailey*, 444 U.S. at 410 (A necessity defense is unavailable "if there was a reasonable, legal alternative to violating the law.").

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[12] We have been informed by the DEA that in December 1997, the DEA referred to the Secretary of HHS a petition by John Gettman to reschedule marijuana because of an asserted lack of a high potential for abuse. HHS has informed us that its evaluation is in the final stages. After completion, the recommendation will be transmitted to the Administrator of the DEA.

[13] Accord *United States* v. *Greene*, 892 F.2d 453, 455 (6th Cir. 1989), cert. denied, 495 U.S. 935 (1990); *United States* v. *Wables*, 731 F.2d 440, 450 (7th Cir. 1984); *United States* v. *Fogarty*, 692 F.2d 542, 547 n.4 (8th Cir. 1982), cert. denied, 460 U.S. 1040 (1983); *United States* v. *Middleton*, 690 F.2d 820, 823 (11th Cir. 1982), cert. denied, 460 U.S. 1051 (1983); *United States* v. *Kiffer*, 477 F.2d 349, 357 (2d Cir.), cert. denied, 414 U.S. 831 (1973).

Rather, respondents contend that Congress has consented to a common law scheme in which respondents in the first instance may decide whether smoking marijuana is medically appropriate. That contention simply flies in the face of Congress's contrary judgment that it is the exclusive province of the Attorney General and the Secretary of HHS, under the statutory and administrative procedures set forth in the CSA, to determine, on a uniform and nationwide basis, whether the state of scientific and medical evidence warrants the use of marijuana for medical purposes—and if so, for which purposes and under what circumstances and restrictions. Congress most assuredly did not relegate that determination to respondents, or to individual courts and juries whenever a defendant asserts a "medical necessity" defense to a charged violation of the Act.[14]

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[14] Respondents argue (Br. in Opp. 24) that this Court should be "particularly reluctant to assume" that Congress has foreclosed a "medical necessity" defense because individuals have a constitutional right to make "personal health decisions." Even if we assume, arguendo, that respondents, who are distributors of marijuana, could justify their own violation of the Act by invoking an asserted constitutional right of individuals to smoke marijuana in certain circumstances, there is, in actuality, no fundamental right to use an unapproved drug for medical treatment. See *Carnohan* v. *United States*, 616 F.2d 1120, 1122 (9th Cir. 1980) (per curiam) (Laetrile); *Rutherford* v. *United States*, 616 F.2d 455, 457 (10th Cir.) (Laetrile), cert. denied, 449 U.S. 937 (1980); *United States* v. *Burzynski Cancer Research Inst.*, 819 F.2d 1301, 1313-1314 (5th Cir. 1987) (antineoplastons), cert. denied, 484 U.S. 1065 (1988); cf. *Washington* v. *Glucksberg*, 521 U.S. 702, 723, 728 (1997) (no fundamental due process right to assisted suicide). Similarly, the courts of appeals have uniformly rejected constitutional challenges to Congress's classification of marijuana as a schedule I drug. See *Greene*, 892 F.2d at 455-456; *United States* v. *Fry*, 787 F.2d 903, 905 (4th Cir.), cert. denied, 479 U.S. 861 (1986); *Fogarty*, 692 F.2d

d. Finally, the recognition of a "medical necessity" defense is inconsistent with the fact that marijuana has not been approved by the FDA based upon a showing that marijuana is safe and effective for *any* medical use. See 21 U.S.C. 321(p), 355. In the 1998 legislation, Congress expressed its continuing adherence to the existing FDA drug approval process by stating that "marijuana * * * has not been proven safe and effective for medical purposes" and that marijuana has "not been approved by the [FDA] to treat any disease or condition." 112 Stat. 2681-760 to 2681-761.[15]

The provision's sponsor, Representative McCollom, explained that the 1998 "statement is important" because, *inter alia*, "[m]ore than 30 States and the District of Columbia have been targeted for possible medical marijuana initiatives," and that such initiatives "have already been passed in California and Arizona." 144 Cong. Rec. H7720 (daily ed. Sept. 15, 1998); see also *id.* at S10,666 (daily ed. Sept. 21, 1998). Congress therefore expressed not only its continuing support for the "existing Federal legal process for determining the safety and efficacy of drugs," but also its opposition to "efforts to circumvent this process by legalizing

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at 547-548 & n.4; *Middleton*, 690 F.2d at 822-823; *Kiffer*, 477 F.2d at 352-357.

[15] Respondents argue (Br. in Opp. 20) that the 1998 legislation "does not have the force of law." Respondents ignore the fact that Congress *already* has barred the unauthorized distribution of marijuana for *all* purposes. The 1998 Act expressly confirms that preexisting prohibition specifically with respect to the use of marijuana for asserted medical purposes. See generally *Accardi* v. *Pennsylvania R.R.*, 383 U.S. 225, 229 (1966) (continuing purpose of Congress reflected in "sense of the Congress" enactment); *Harris* v. *United States*, 359 U.S. 19, 22 n.8 (1959) (continuing purpose of Congress reflected in subsequently-enacted legislation).

marijuana * * * *for medicinal use* without valid scientific evidence and the approval of the Food and Drug Administration." 112 Stat. 2681-761 (emphasis added). The 1998 Act thus refutes the notion that courts and juries may allow the federally-unregulated distribution of marijuana based on a common law principle that Congress would have sanctioned such distribution had it considered the competing values at stake.

3. In *United States* v. *Rutherford*, 442 U.S. 544 (1979), this Court considered a highly analogous issue and held that a claim of medical need for a drug cannot override Congress's legislative judgment that the drug not be distributed absent a finding by the FDA under the FDCA that the drug is safe and effective. In *Rutherford*, a class of terminally ill cancer patients and their spouses brought suit to enjoin the government from interfering with the interstate shipment and sale of Laetrile, a drug that had not been approved by the FDA. The district court granted the requested relief, and the Tenth Circuit affirmed, holding that the safety and effectiveness protections of the FDCA had no reasonable application to terminally ill cancer patients because those patients, by definition, would die of cancer regardless of their treatment. *Id.* at 548-549.

This Court unanimously reversed. The Court rejected the Tenth Circuit's determination that an exemption from the Act was justified because the safety and effectiveness standards could have no reasonable application to terminally ill cancer patients, explaining that, "[u]nder our constitutional framework, federal courts do not sit as councils of revision, empowered to rewrite legislation in accord with their own conceptions of prudent public policy. * * * Whether, as a policy matter, an exemption should be created is a question for legislative judgment, not judicial inference." 442

U.S. at 555, 559. The Court also reasoned that the FDCA "makes no special provision for drugs used to treat terminally ill patients," and that "[w]hen construing a statute so explicit in scope," it is incumbent upon the courts to give it effect. *Id.* at 551.

Finally, the Court reasoned that the recognition of a non-statutory exception to the federal drug laws could wreak havoc on Congress's aim to avert the dangers associated with the unregulated use and distribution of unapproved drugs:

> It bears emphasis that although the Court of Appeals' ruling was limited to Laetrile, its reasoning cannot be so readily confined. To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked.

442 U.S. at 557-558.

The Court's holding and reasoning in *Rutherford* apply with equal force in this case, where Congress has expressed its unambiguous intent in the CSA to ban the unauthorized distribution of marijuana, even for medical purposes. By sanctioning the ongoing and open violation of the federal drug laws, the court of appeals' decision opens the way for manufacturers, distributors, or users of other schedule I drugs (such as heroin or LSD)—which have not been approved by the FDA for *any* medical use and which are controlled under the CSA because of their "high potential for abuse" and "lack of accepted safety for use" even "under medical supervision"—to invoke "medical necessity" as a defense to a violation of the nation's drugs law. The re-

cognition of a "medical necessity" defense under the CSA therefore would significantly undermine the Act's paramount policy to protect the public health and safety. See 21 U.S.C. 801(2).

4. Respondents contend (Br. in Opp. 6, 21-22, 25-29) that Congress's determination that marijuana has no accepted medical use is harmonious with their unregulated distribution of marijuana because the statutory phrase "currently accepted medical use in treatment" (21 U.S.C. 812(b)(1)(B)) serves a different purpose than that served by the common law defense of "medical necessity." Respondents reason (Br. in Opp. 26, 28) that Congress placed marijuana in schedule I to restrict its distribution to the "general public," while a "medical necessity" defense permits the distribution of marijuana only when patients and their physicians "jointly agree" that "generally accepted treatments are ineffective." Those contentions are legally irrelevant and, in any event, are fundamentally mistaken.

a. It is precisely because Congress has determined that marijuana has no "currently accepted medical use" and placed that drug in schedule I that Congress has emphatically foreclosed a distributor from ignoring the CSA on the ground that the recipients claim a medical need to smoke marijuana. Thus, the CSA imposes an absolute ban on the distribution of marijuana—*including* distribution for asserted medical purposes—outside the strict confines of the Act itself. See pp. 19-20, *supra*. And even for drugs listed in schedules II through V, which Congress or the Attorney General has determined *do* have an accepted and safe medical use, 21 U.S.C. 812(b)(2)-(5), and for which the CSA *does* permit physicians to determine whether particular patients have a medical need for the drug, 21 U.S.C. 829, the CSA imposes strict controls on physicians and phar-

macies before they may distribute or dispense the drug. See pp. 20-23, *supra*. That comprehensive set of statutory controls leaves no room for the distribution of marijuana for asserted medical purposes by relying on a common law defense of necessity.

b. In any event, the notion that respondents may dispense marijuana for medical use *is* inconsistent with the CSA's determination that marijuana has no "currently accepted medical use" (21 U.S.C. 812(b)(1)(B)), as well as the absence of a finding by the FDA under the FDCA that marijuana is "safe and effective" for *any* intended medical use (21 U.S.C. 355). See also 112 Stat. 2681-760 (finding that marijuana is "unsafe, even under medical supervision"; "lack[s] any currently accepted medical use"; and has never been approved by the FDA as "safe and effective" "to treat any disease or condition"). Respondents cannot credibly maintain that Congress intended to permit defendants charged with violating the CSA to persuade courts and juries that smoking marijuana "has proven effective in relieving [patients' medical] conditions or symptoms" (Br. in Opp. 22) when Congress already has most emphatically determined that marijuana, in fact, has *not* been "proven" to be safe or effective to treat any medical condition.[16]

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[16] Nor is it plausible to suggest (Br. in Opp. 26-29) that recognition of a "medical necessity" defense would be confined to a limited number of individuals or class of medical conditions. For instance, on May 19 and October 22, 1997, two undercover DEA agents purchased marijuana from respondents by presenting phony physician statements asserting that the agents suffered from post-traumatic stress disorder and menstrual cramps. J.A. 48, 70. Moreover, on May 21, 1998, approximately 200 persons visited OCBC to obtain marijuana to treat a wide variety of conditions, including AIDS, cancer, glaucoma, pain, headaches,

c. Similarly, to allow courts and juries to consider whether marijuana is medically "efficacious" or consistent with "good medical practice" for a given individual (Br. in Opp. 28, 29) would subvert Congress's intent to bar the medical use of a schedule I drug until rigorous scientific proof establishes that the drug no longer meets the statutory criteria for listing under that schedule. Before marijuana may be removed from schedule I, the Attorney General, in consultation with the Secretary of HHS, must determine that marijuana has a "currently accepted medical use in treatment in the United States." 21 U.S.C. 812(b)(2)(B), (3)(B), (4)(B) and (5)(B). In making that determination, the Attorney General and the Secretary must consider the "[s]cientific evidence of [drug's] pharmacological effect" and "state of current scientific knowledge regarding the drug." 21 U.S.C. 811 (c)(2) and (3).

Applying those provisions, in 1992, the DEA Administrator concluded in response to a petition to reschedule marijuana that marijuana has no currently accepted medical use and therefore should not be transferred to schedule II. 57 Fed. Reg. 10,499. The Administrator also delineated the five characteristics that a drug must have in order to find that it has a currently accepted

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arthritis, rotator cuff syndrome, stress, depression, paranoid schizophrenia, and anxiety. See J.A. 32-39. Similarly, in requesting the district court to modify its injunction in light of the Ninth Circuit's decision, respondents submitted the affidavits of persons who asserted that they used marijuana for medical conditions such as lupus, irritable bowel syndrome, cystitis, cancer, arthritis, insomnia, Hepatitis C, AIDS, scoliosis, esophageal stricture, Meniere's disease, sarcoidosis, leg and back spasms, migraine headaches, depression, and bulimia. Vol. 1 Declarations in Support of Defendants' Motion to Dissolve or Modify Preliminary Injunction Order (filed May 30, 2000).

medical use: (1) the drug's chemistry must be known and reproducible; (2) there must be adequate studies proving the drug's safety in treating a specific, recognized disorder; (3) there must be adequate and well-controlled studies proving the drug's efficacy in treating a specific, recognized disorder; (4) the drug must be accepted by qualified experts; and (5) the scientific evidence must be widely available. *Id.* at 10,506. Based on a consideration of those five factors, as well as the lack of reliable scientific evidence supporting the medical use of marijuana for any medical condition, *id.* at 10,500-10,505, the Administrator concluded that "[m]arijuana fails all five points of the test." *Id.* at 10,507.

The Administrator also addressed the testimony of individuals and physicians who opined that marijuana had a medical use, explaining that "[l]ay testimonials, impressions of physicians, isolated case studies, random clinical experience, reports so lacking in details they cannot be scientifically evaluated, and all other forms of anecdotal proof" do not provide a sufficiently reliable basis under the CSA for assessing the safety and efficacy of marijuana or any other drug. 57 Fed. Reg. at 10,505. The Administrator's determinations were upheld by the District of Columbia Circuit, which concluded that the Administrator reasonably insisted on "rigorous scientific proof over anecdotal evidence, even when reported by respected physicians." *Alliance for Cannabis Therapeutics* v. *DEA*, 15 F.3d 1131, 1137 (1994). The court of appeals also reasoned that the Administrator had properly relied on "the testimony of numerous experts that marijuana's medicinal value has never been proven in sound scientific studies," and that "[t]he Administrator reasonably accorded more weight to the opinions of these experts than to the anecdotal

testimony of laymen and doctors." *Ibid.* The court of appeals therefore concluded that the Administrator's "findings are consistent with the view that only rigorous scientific proof can satisfy the CSA's 'currently accepted medical use' requirement." *Ibid.*

Congress in the FDCA similarly has rejected reliance on the subjective views of individual physicians and patients to support the use of a new drug, such as marijuana, for medical use. The FDCA requires that, before the FDA may approve a new drug, the drug must be proven safe through "adequate tests by all methods reasonably applicable" and proven effective based on "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." 21 U.S.C. 355(d); accord 112 Stat. 2681-760 (new drug "must meet extensive scientific and medical standards established by the [FDA] to ensure it is safe and effective"). The FDA therefore will not consider "[i]solated case reports, random experience, and reports lacking the details which permit scientific evaluation." 21 C.F.R. 314.126(e); see *Rutherford*, 442 U.S. at 550 n.7 (The FDCA requires "an 'expert consensus' on safety and effectiveness founded upon 'substantial evidence' as defined in [21 U.S.C. 355(d)]."); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973) (The FDA's "strict and demanding standards," which "bar[] anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug, are amply justified by the legislative history" of the FDCA, which reflects "a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous.").

At bottom, the recognition of a "medical necessity" defense would bypass altogether the statutory pro-

cedures that Congress enacted for the rescheduling of a drug by the Attorney General and for the approval of a drug by the FDA, in favor of a judicially sanctioned system in which individual patients, physicians, and cannabis clubs decide whether marijuana is safe and effective for medical use. Congress plainly did not intend to permit a result that would render so "wholly nugatory" (*Bailey*, 444 U.S. at 416 n.11) the statutory framework of the CSA.

5. Respondents assert (Br. in Opp. 18) that the CSA's history shows that "Congress placed cannabis only tentatively in Schedule I" because Congress "did not have a firm understanding of cannabis." Respondents observe (*id.* at 18-20) that the House Report stated that "[t]he extent to which marihuana should be controlled is a subject upon which opinions diverge widely" (H.R. Rep. No. 1444, *supra*, Pt. 1, at 12); that the Secretary of Health, Education, and Welfare recommended to Congress that marijuana "be retained within schedule I" until the completion of further studies (*id.* at 13); and that a Commission established by Congress recommended the decriminalization of casual distribution of small amounts of marijuana for no remuneration or insignificant remuneration not involving profit (National Comm'n on Marihuana & Drug Abuse, *Marihuana: A Signal of Misunderstanding* 152 (Mar. 1972) (*Marihuana*)).[17] Nothing in that history,

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[17] The Commission explained that many users of marijuana had been given the drug by a "friend, acquaintance or family member," and that such "casual transfers" should be treated "as the functional equivalent of possession." *Marihuana* 157, 158. The Commission also recommended that there should be no federal criminal sanction for possession of marijuana for personal use, reasoning that federal agencies "have left possession enforcement to the states * * * to maximize the use of [federal] enforcement re-

however, casts doubt on the fact that Congress placed marijuana in schedule I, where it has been listed for 30 years, knowing full well that it was categorically banning the distribution of marijuana for any purpose, including asserted medical uses, except as authorized by the CSA. See H.R. Rep. No. 1444, *supra*, Pt. 1, at 13 ("marihuana is listed under schedule I, as subject to the most stringent controls under the bill"); see also 116 Cong. Rec. 1664 (1970) (statement of Sen. Hruska) (noting that marijuana was placed in schedule I because it "comes squarely within the criteria of that schedule," *i.e.*, "highest abuse potential" and "little or no accepted medical use in this country").

We do not dispute that Congress contemplated the possibility that further research could produce scientific evidence that would support the use for medical purposes of certain substances, including marijuana, that Congress initially listed in schedule I. But Congress directed that, to be credited and given weight under the CSA, any such research must be presented, not to organizations like OCBC, or to courts and juries in individual proceedings brought by the United States to enforce the CSA, but to the Attorney General and the Secretary of HHS to consider under the exclusive standards and administrative procedures set forth in the CSA itself. 21 U.S.C. 811, 812; see pp. 23-25, *supra*.[18]

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sources for major priorities," such as eliminating marijuana traffickers and suppliers. *Id.* at 155-156. Notwithstanding the Commission's recommendations, Congress in the CSA has maintained criminal penalties for both the possession of marijuana and the casual distribution of marijuana that does not involve profit. See 21 U.S.C. 841(a)(1), 844(a).

[18] There is no petition pending before the DEA to reschedule marijuana on the ground that marijuana has any accepted medical use. Cf. note 12, *supra*. We do note, however, that studies are

The history of the CSA therefore provides no basis whatsoever for inferring a congressional intent to permit the distribution of marijuana outside the framework of the CSA, based on an asserted medical need to smoke it.

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underway that involve the human health effects of marijuana. We are informed by the DEA that two researchers are currently registered with the DEA to conduct clinical research under 21 U.S.C. 823(f) into the human health effects of smoked marijuana. Moreover, on May 21, 1999, HHS announced new guidance for the provision of marijuana for medical research. See *Kuromiya* v. *United States*, 78 F. Supp. 2d 367, 374 (E.D. Pa. 1999). We also note that, in 1999, the Institute of Medicine reviewed the existing scientific evidence concerning possible medical uses of marijuana and recommended that further research be devoted, not to developing marijuana as a licensed drug, but to developing a method of delivering cannabinoids without the serious adverse health consequences associated with smoking marijuana. See Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base* 10-11 (Janet E. Joy et al. eds. 1999) (noting that "[b]ecause marijuana is a crude THC delivery system that also delivers harmful substances, smoked marijuana should generally not be recommended for medical use," and recommending "clinical trials * * * to serve as a first step toward the development of nonsmoked rapid-onset cannabinoid delivery systems"). One method of delivery of cannabinoids currently available is Marinol®, which contains a synthetic form of THC in pill form. Marinol® has been approved by the FDA for the treatment of nausea and vomiting associated with cancer chemotherapy and for the treatment of anorexia associated with weight loss in AIDS patients. See 64 Fed. Reg. 35,928 (1999). On July 2, 1999, DEA transferred Marinol® from schedule II to schedule III, thereby lessening the regulatory restrictions on its use. *Ibid.*

B. Courts Lack The Equitable Discretion Under The CSA To Permit The Unauthorized Distribution Of Marijuana To Persons Who Assert A Medical Necessity To Use It

1. In holding that "medical necessity" is a "legally cognizable defense" (App. 8a), the court of appeals did not attempt to reconcile a "medical necessity" defense either with the text, structure, or purposes of the CSA, or with the 1998 legislation disapproving any attempt to legalize marijuana for medicinal use outside the existing framework of the CSA and the FDCA. Rather, the court of appeals explained that it saw "no indication that the 'underlying substantive policy' of the [CSA] mandates a limitation on the district court's equitable powers" "to formulate appropriate relief when and if injunctions are sought" under 21 U.S.C. 882(a). App. 9a (quoting *Northern Cheyenne Tribe* v. *Hodel*, 851 F.2d 1152, 1156 (9th Cir. 1988)). The court of appeals took the view that the district court abused its discretion first in failing to consider what the court of appeals identified as "a strong public interest" in the availability of marijuana for medicinal purposes, and second in finding that an injunction against marijuana distribution could not be supported by the government's "general interest in enforcing its statutes." *Id.* at 9a, 11a.

Those conclusions, however, conflict with this Court's precedents concerning the limits of a district court's equitable discretion in fashioning an injunction. This Court has long held that a district court sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginian Ry.* v. *System Fed'n No. 40*, 300 U.S. 515, 551 (1937); see also *Albemarle Paper Co.* v. *Moody*, 422 U.S. 405, 417

(1975) ("when Congress invokes the Chancellor's conscience to further transcendent legislative purposes, what is required is the principled application of standards consistent with those purposes and not 'equity [which] varies like the Chancellor's foot'").

Those principles were reaffirmed in *TVA* v. *Hill*, 437 U.S. 153 (1978), in which this Court held that, in examining whether to enter injunctive relief, a court must be mindful that

> it is * * * emphatically * * * the exclusive province of the Congress not only to formulate legislative policies and mandate programs and projects, but also to establish their relative priority for the Nation. Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the Executive to administer the laws and for the courts to enforce them when enforcement is sought.

Id. at 194.[19] The Court similarly has explained that although it will "not lightly assume that Congress meant to restrict the equitable powers of the federal courts," "where Congress has made its intent clear, '[the Court] must give effect to that intent.'" *Miller* v. *French*, 120 S. Ct. 2246, 2253 (2000) (quoting *Sinclair Refining Co.* v. *Atkinson*, 370 U.S. 195, 215 (1962)); see also *Weinberger* v. *Romero-Barcelo*, 456 U.S. 305, 313 (1982) ("[A] statute in so many words, or by a necessary and inescapable inference, [may] restrict[] the court's

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[19] One commentator has explained that *Hill* "established that a court cannot use equitable discretion as a pretext for reordering priorities that Congress already has set." Daniel A. Farber, *Equitable Discretion, Legal Duties, and Environmental Injunctions*, 45 U. Pitt. L. Rev. 513, 519 (1984).

jurisdiction in equity.") (quoting *Porter* v. *Warner Holding Co.*, 328 U.S. 395, 398 (1946)).

In similar circumstances, this Court in *Rutherford* (discussed at pp. 27-28, *supra*) held that the Tenth Circuit erred in holding that a district court had the power to enter an injunction permitting the use of an unapproved drug (Laetrile) by terminally ill cancer patients, even under a doctor's supervision, because the FDCA "makes no special provision for drugs used to treat terminally ill patients." 442 U.S. at 551.[20] The CSA similarly "makes no special provision" for the unauthorized distribution of drugs for medical use, no matter how fervently individual patients or doctors believe that a drug has a medical use. Congress already has considered the public interest, balanced the relevant medical and other policy considerations, and made the fundamental policy choice that "[t]he illegal * * * distribution[] and * * * improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people." 21 U.S.C. 801(2). Congress therefore has concluded that, unless and until the Attorney General removes marijuana from schedule I, the drug has no accepted medical or safe use and may not be distributed outside of a strictly controlled research project under the CSA. See pp. 19-20, *supra*. A district court therefore lacks the discretion, based on its own perception of the public interest and its own weighing of possible medical bene-

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[20] Indeed, the Court in *Rutherford* cited *Hill* with approval, observing that "[e]xceptions to clearly delineated statutes will be implied only where essential to prevent absurd results or consequences obviously at variance with the policy of the enactment as a whole." 442 U.S. at 552 (internal quotation marks omitted); accord *id.* at 555.

fits against the potential for abuse, to craft an injunction under the CSA that exempts from the injunction's reach the distribution of marijuana for medical use.

2. In defending the judgment of the court of appeals, respondents argue (Br. in Opp. 13-17) that a court may decline to enjoin a cannabis distribution club from distributing marijuana in blatant violation of the CSA, whether or not "medical necessity" is a valid defense under the Act. Not even the court of appeals, however, embraced that radical proposition. See App. 8a (finding that the district court failed to "take into account a legally cognizable defense that likely would pertain in the circumstances").[21]

Nor is such a proposition supported by any decision of this Court. As previously explained, district courts sitting in equity cannot "ignore the judgment of Congress" that is "deliberately expressed in legislation." *Virginian Ry.*, 300 U.S. at 551; see also *Miller*, 120 S. Ct. at 2253; *Hill*, 437 U.S. at 194. Respondents therefore erroneously rely on this Court's decisions in *Romero-Barcelo*, *supra*, and *Hecht Co.* v. *Bowles*, 321 U.S. 321 (1944). Those decisions confirm that a court may not exercise its equitable discretion—which is intended to allow a court to decide how best to assure *compliance* with a congressional act—so as to countenance ongoing *violation* of a congressional act.

In *Romero-Barcelo*, the Court held that under the Federal Water Pollution Control Act, the district court retained discretion in appropriate circumstances to

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[21] The district court's modification of its injunction likewise was premised only on the assumption that, because "medical necessity" is a valid defense under the CSA, a district court has the equitable power to permit the medical use of marijuana in violation of the CSA. App. 13a.

order relief other than an immediate injunction barring all discharge of pollutants that did not comply with the Act if that other relief would "achieve compliance" with the Act. 456 U.S. at 307. The district court found that the Navy had committed "technical violations" of the statute, without "causing any 'appreciable harm' to the environment," by occasionally discharging ordnance into the sea without a permit. *Id.* at 310. The district court ordered the Navy to apply for the requisite permit, but declined to enjoin naval operations, concluding that an injunction was not necessary to ensure compliance. *Ibid.* This Court found that "although the District Court declined to enjoin the discharges, it neither ignored the statutory violation nor undercut the purpose and function of the permit system." *Id.* at 315. The Court further observed that, "[r]ather than requiring a district court to issue an injunction for any and all statutory violations, the FWPCA permits the district court to order that relief it considers necessary *to secure prompt compliance with the Act.*" *Id.* at 320 (emphasis added).

Similarly, in *Hecht Co.*, the district court declined the government's request for an injunction against a defendant that had violated statutory price controls. The district court reasoned that it had "no doubt" that the defendant acted in "good faith and diligence" in attempting to comply with the statute, that the defendant had taken "vigorous steps" to correct and prevent recurrence of its mistakes, and that issuance of an injunction would have "no effect" on ensuring future compliance with the statute. 321 U.S. at 325, 326. This Court concluded that under the statute "there is some room for the exercise of discretion on the part of the court," and further observed that other remedial orders short of injunction might have been consistent with the

statute. *Id.* at 328. The Court made clear, however, that courts have the responsibility to enforce the statute and that "their discretion under [the statute] must be exercised in light of the large objectives of the Act," "[f]or the standards of the public interest, not the requirements of private litigation, measure the propriety and need for injunctive relief." *Id.* at 331.[22]

Those decisions therefore provide no support for a district court, under its authority "to *enjoin* violations" of the CSA, 21 U.S.C. 882(a) (emphasis added), to *allow* the ongoing illegal distribution of marijuana, based on the court's perception that the public interest supports the use of marijuana for medical purposes. As we have explained, Congress already has weighed what it deemed to be the relevant public-interest considerations and categorically determined that marijuana may

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[22] Contrary to respondents' suggestion (Br. in Opp. 17), *Amoco Production Co.* v. *Village of Gambell*, 480 U.S. 531 (1987), likewise does not support the invocation of a district court's equitable power to permit respondents to distribute marijuana in violation of the CSA. The Court in *Amoco* held that a district court did not err in declining to issue an injunction to bar exploratory drilling on Alaskan public lands, because the district court's decision "did not undermine" the policy of the Alaska National Interest Lands Conservation Act, 16 U.S.C. 3120, "to protect Alaskan subsistence resources from unnecessary destruction." 480 U.S. at 544, 546. The Court reasoned that the exploration activities would not significantly restrict the subsistence uses of the land; that the denial of injunctive relief did not deprive the government of its ability to control and shape the leasing process; and that Congress had expressed a policy favoring continued oil exploration in another federal statute. *Id.* at 544-545. Nothing in the Court's decision in *Amoco* suggests that a court may use its equity power to determine that the public interest supports conduct that is fundamentally antithetical to the text, structure, and policy of the statute that the court is supposed to enforce.

not be distributed for any purpose, "[e]xcept as authorized" by the Act, 21 U.S.C. 841(a)(1). Congress therefore has "deliberately expressed" (*Virginian Ry.*, 300 U.S. at 551) its intention to foreclose a district court from using the power conferred under 21 U.S.C. 882(a) to permit the ongoing and illegal distribution of marijuana for asserted medical purposes.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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JANUARY 2001